



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John Kevin COLLINS et al

Serial No.: 10/783020

Group Art Unit: 1651

Filed:

February 23, 2004

For: BIFIDOBACTERIUM IN THE TREATMENT

OF INFLAMMATORY DISEASE

THIRD INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the above-identified application.

Copies of all references can be found in the copending application Serial No.



Respectfully submitted,

JACOBSON HOLMAN PLLC

3y: ___

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Atty. Dkt. No.: P66879US3

Date: July 27, 2004

10/376602.

400 SEVENTH STREET, N.W.

WASHINGTON, D.C. 20004-2201

ATTY. DOCKET NO.: <u>P66</u>			P668	66879US3 GF			GROUP ART UNIT:		1651			
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SERIAL NO.:	
APPLICANT(S):	COLLINS TODAY'S DATE: July 27, 2004
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OTHER	ART (Including Author, Title, Date, Pertinent Pages, Etc.)
AW	Kühn et al, CELL, Vol 75, 10/22/93, pqs. 263-274,
	Interleukin-10-Deficient Mice Develop Chronic Enterocolitis
AX	Marteau et al, FEMS MICROBIOLOGY REVS 12, 1993, pqs. 207-220,
	Potential of using lactic acid bacteria for therapy and
AY	Rumney et al, CARCINOGENESIS, Vol 14, No 1, 1993, pqs. 79-84,
	Effects of risk-associated human dietary macrocomponents on
AZ	O'Sullivan et al, IRISH JOUR OF MED SCI, PROC OF THE IRISH SOC
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AA1	Adachi, THE LACTIC ACID BACTERIA, Vol 1, 1992, pqs. 233-261,
	Lactic Acid Bacteria and the Control of Tumours
AB1	Chauviere et al, JOURNAL OF GENERAL MICROBIOLOGY 138, 1992, pgs.
	1689-1696, Adhesion of human Lactobacillus acidophilus strain
AC1	O'Sullivan et al, TRENDS IN FOOD SCIENCE & TECH, Vol 31, Dec.
	1992, pgs. 309-314, Probiotic bacteria: myth or reality
AD1	Tancrede, EUR J CLIN MICROBIOL INFECT DIS, Vol 11, No 11, Nov.
	1992, pgs. 1012-1015, Role of Human Microflora in Health and
AE1	Vaughan et al, JOUR OF APPL BACTERIOLOGY 73, 1992, pgs. 299-308,
	Identification and characterization of helveticin V-1829, a
AF1	Malefyt et al, J EXP MED, Vol 174, Oct. 1991, pgs. 915-924,
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AG1	O'Sullivan et al, IRISH SOC OF GASTROENTEROLOGY, Proc in Dublin
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AH1	Mangan et al, JOUR OF IMMUNOLOGY, Vol 146, No 5, pgs. 1541-1546,
	Mar 1, 1991, Lipopolysaccharide, Tumor Necrosis Factor- α and
AI1	Toba et al, LTRS IN APPL MICROBIOLOGY 12, 1991, pqs. 228-231,
	Potential of Lactobacillus gasseri isolated from infant
AJ1	Wahl et al, JOUR OF IMMUNOLOGY, Vol 146, No 1, pgs. 95-100, Jan
	1, 1991, IFN-y Inhibits Inflammatory Cell Recruitment and the
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	AK1	Cicco et al, BLOOD, Vol	75, No 10, 1990, pgs	. 2049-2052,
		Inducible Production of	Interleukin-6 by Hum	an
	AL1	Donnelly et al, JOUR OF	IMMUNOLOGY, Vol 145,	No 2, Jul 15, 1990,
		pgs. 569-575, Different	ial Regulation of IL-	1 Production in
	AM1	Gatanaga et al, PROC NA	TL ACAD SCI, Vol 87,	pgs. 8781-8784, Nov.
		1990, Purification and		
	AN1	Gilliland, FEMS MICROBI	OLOY REV 87, pgs. 175	-188, 1990, Health
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	A01	Fuller, JOUR OF APPL BA	CTERIOLOGY 66, 1989,	pgs. 365-378,
		Probiotics in man and a	nimals	
	AP1	Dinarello et al, REV OF	INFECTIOUS DIS, Vol	10, No 1, Jan/Feb
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	AQ1	Ferrante et al, INT ARC	HS ALLERGY APPL IMMUN	86, 1988, pgs. 82-
		91, Effects of Tumour N	ecrosis Factor Alpha	and Interleukin-1
	AR1	Kim, CULTURED DAIRY PRO	D JOUR, Aug 1988, pgs	. 6-9, Character-
		<u>ization of Lactobacilli</u>	and Bifidobacteria a	s applied to
	AS1	Shanahan et al, INFLAMM	ATORY BOWEL DISEASE	.INTL CONGRESS, 1988
		pgs. 101-106, In vivo p	rimed cytotoxic T cel	ls in inflammatory
	AT1	Bachwich et al, BIOCHEM	AND BIOPHYS RES COMM	UN, Vol 136, No 1,
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	AU1	Wong et al, NATURE, Vol	323, Oct 1986, pgs.	816-819, Antiviral
		effects of recombinant	tumour necrosis facto	r in vitro
 	AV1	Anand et al, CULT DAIRY	PROD 2, 1985, pgs. 2	1 and 23, Anti-
		bacterial Activity Asso	<u>ciated with Bifidobac</u>	cterium bifidum - II
	AW1	Kawakami et al, JOUR OF	IMMUNOLOGY, Vol 132,	No 5, May 1984, A
		Group of Bactericidal F	actors Conserved by V	ertebrates for
	AX1	Tannock, HUMAN INTESTIN	<u>AL MICROFLORA IN HEAL</u>	TH & DISEASE, 1983,
		pgs. 517-539, Effect of	Dietary and Environm	ental Stress on
EXAMINER			DATE CONSIDERED	

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AY1	Savage, IN: MICROBIAL ECOLOGY OF THE GUT, 1977, pgs. 277-310,
	Interaction between the host and its microbes
AZ1	Crabbe et al, INT ARCH ALLERGY 34, 1968, pgs. 362-375, The
	Normal Microbial Flora as a Major Stimulus for Proliferation
AA2	O'Mahony et al, PROC OF BRITISH NUTRITIONAL FOUNDATION, 2000,
	pgs. 63-70, Probiotic Bacteria and the Human Immune System
AB2	McBrearty et al, PROC OF BRITISH NUTRITIONAL FOUNDATION, 2000,
	pgs. 97-107, Probiotic Bifidobacteria and Their Identification
AC2	Blum et al, TRENDS IN FOOD SCI & TECH 10, 1999, pgs. 405-410,
	Adhesion studies for probiotics: need for validation and
AD2	Collins et al, GASTROENTEROLOGY, Vol 116, No 4, Apr 1999, 1 pg.
	A Controlled Trial of Probiotic Treatment of IL-10 Knockout Mice
AE2	Collins et al, GASTROENTEROLOGY, Vol 116, No 4, Apr 1999, 1 pg.
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AF2	Darveau, NATURE BIOTECHNOLOGY, Vol 17, Jan 1999, pg. 19,
	Infection, inflammation, and cancer
AG2	Dunne et al, GASTROENTEROLOGY, Vol 116, No 4, Apr 1999, 2 pgs.
	Epithelial Adhesion of Probiotic Microorganisms In Vitro and
AH2	O'Mahony et al, IR J MED SCI, Vol 168, No 5, 1999, Consumption
	of Probiotic Bacteria Ameliorates Enterocolitis in IL-10
AI2	O'Mahony et al, SIXTH SYMP ON LACTIC ACID BACTERIA, Sept 19/
	23, 1999, 2 pgs., Probiotic Treatment of Enterocolitis in
AJ2	Gardiner et al, SIXTH SYMP ON LACTIC ACID BACTERIA, Sept 19/
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AK2	Gardiner et al, SIXTH SYMP ON LACTIC ACID BACERTIA, Sept 19/
	23, 1999, 2 pgs., Preparation of Spray Dried Powders
AL2	O'Mahony et al, IRISH JOUR OF MED SCI, Nov 26/27, 1999, UCC118
	Modulates Proinflammatory Cytokine Production in Vitro
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AM2 Gardiner et al, J DAIRY SCI Vol 82, No 7, 1999, pqs. 1379-138	,
Evaluation of Cheddar Cheese as a Food Carrier for Delivery	
AN2 Gardiner et al, J AGRIC FOOD CHEM, Vol 47, 1999, pgs. 4907-49	6,
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AO2 Mattila-Sandholm et al, TRENDS IN FOOD SCI & TECH, Vol 10, 19	9,
pgs. 393-399, Probiotics: towards demonstrating efficacy	
AP2 McCracken et al, PROBIOTICS A CRITICAL REVIEW, 1999, pqs. 85-	13
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AQ2 Murphy et al, GASTROENTEROLOGY, Vol 116, No 4, 1999, 2 pgs.,	
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AR2 Murphy et al, MICROBIAL ECOLOGY IN HEALTH & DISEASE, 1999, pg	
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AS2 Present et al, NEW ENGLAND JOUR OF MED, Vol 340, No 18, May 6	
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AT2 Reddy, AMER SOC FOR NUTR SCI, 1999, pgs. 1478S-1482S, Possible	:
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AU2 O'Halloran et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, 3 pgs	,
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AV2 Flynn et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, 3 pqs.,	
Isolation and Characterisation of the Novel Antibacterial	
AW2 Charteris et al, JOUR OF FOOD PROTECTION, Vol 61, No 12, 1998	
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AX2 Charteris et al, Jour of APPL MICROBIOLOGY, Vol 84, 1998, pgs	
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AY2 Collins et al, INT DAIRY JOUR 8, 1998, pgs. 487-490, Selection	
of Probiotic Strains for Human Applications	
AZ2 Gardiner et al, APPL AND ENVIR MICROBIOLOGY, Vol 64, No 6, 19	8,
pgs. 2192-2199, Development of a Probiotic Cheddar Cheese	
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	OTHER	ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
	AA3	Gardiner et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, 3 po	qs.,
		Characterisation of Cheddar Cheese Harboring Probiotic	
	AB3	Kato et al, LIFE SCIENCES, Vol 63, No 8, 1998, pgs. 635-64	44,
		Suppressive Effects of the Oral Administration of	
	AC3	Morrisey et al, IR JOUR OF MED SCI, Vol 167, Supp No 8, 19	998,
		2 pgs., Election of a Probiotic Strain to Modify	
	AD3	Murphy et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Long-	term
		Colonisation with Lactobacillus salivarius subsp. salivar	ius
	AE3	Feency et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Lack	of
		Specific Systemic Immune Response on Oral Consumption of.	• •
	AF3	O'Riordan et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Ase	ess-
		ment of Bifidobacterium Strains for antimicrobial and	
	AG3	Collins, FUNCTIONAL FOOD RESEARCH IN EUROPE, Oct 1/2, 1998	8, pg.
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	AH3	Collins et al, FUNCTIONAL FOOD RESEARCH IN EUROPE, Oct 1/2	2, <u>1998</u>
		pgs. 40-41, Demonstration of Probiotic Function in a Doub	le
	AI3	O'Riordan et al, JOUR OF APPL MICROBIOLOGY, Vol 85, 1998,	pgs.
		103-114, Evaluation of bifidobacteria for the production of	of
	AJ3	Panwala et al, JOUR OF IMMUNOLOGY, Vol 161, 1998, pgs. 57	33-
		5744, A Novel Model of Inflammatory Bowel Disease: Mice	•
	AK3	Raychaudhuri et al, NAT BIOTECHNOL, Vol 16, 1998, pgs. 103	25-1031
		Fully mobilizing host defense: Building better vaccines	
	AL3	Salminen et al, INTL JOUR OF FOOD MICROBIOLOGY 44, 1998, 1	pgs.
		93-106, Demonstration of safety of probiotics - a review	
	AM3	Cong et al, GASTROENTEROLOGY 115, 1998, pgs. 1595-1600, Go	enes,
		Bacteria, and T Cells: Ingredients for Inflammatory Bowel	
	AN3	Stallmach et al, TRENDS IMMUNOLOGY TODAY, Vol 19, No 10, O	Oct.
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	AO3	Stanton et al, INT DAIRY JOUR 8, 1998, pgs. 491-496, Probiotic
	AP3	Cheese Janggang, FOR MED SCI: CLINIC BIOCHEM & MED TEST, Vol 19(5),
	AQ3	1998, pgs. 231-233, Immunopotentiating Activity of Gionchetti et al, GASTROENTEROLOGY INTL, Vol. 11, Supp 1, 1998, pqs. 108-110, Microflora in the IBD Pathogenesis - Possible
	AR3	Steidler et al, INFECTION AND IMMUNITY, Jul 1998, pgs. 3183-3189 Mucosal Delivery of Murine Interleukin-2 (IL-2) and IL-6 by
	AS3	Brandtzaeg et al, SPRINGER SEMIN IMMUNOPATHOL 18, 1997, pgs. 555
	AT3	-589, Immunopathology of human inflammatory bowel disease Charteris et al, INTL JOUR OF FOOD MICROBIOLOGY 35, 1997, pgs.
	AU3	1-27, Selective detection, enumeration and identification of Gahan et al, JOUR OF LEUKOCYTE BIOLOGY, Vol 62, Dec 1997, pgs. 726-732, Innate resistance to Listeria monocytogenes in tumor
	AV3	Ramos et al, ANNU REV REV MICROBIOL 51, 1997, pgs. 341-373, Transcriptional Control of the <i>Pseudomonas</i> Tol Plasmid
	AW3	Leonard et al, CRITICAL REVIEWS IN IMMUNOLOGY 17, 1997, pgs. 545-553, Regulation of the Inflammatory Response in Animal Models
	AX3	Lucey et al, FOOD SCI & TECH TODAY 11(4), 1997, pgs. 230-233, Developing Fields in Food Biotechnology
	AY3	McFarland et al, ANAEROBE 3, 1997, pgs. 73-78, Pharmaceutical Probiotics for the Treatment of Anaerobic and Other Infections
	AZ3	O'Riordan et al, FEMS MICROBIOLOGY LTRS 156, 1997, pgs. 259-264, Determination of genetic diversity within the genus
	AA4	Schmitt et al, CHEM IMMUNOL 68, 1997, pgs. 70-85, The Immuno- stimulatory Function of IL-12 in T-Helper Cell Development
	AB4	Shanahan et al, GASTROENTEROLOGY 112, 1997, pgs. 1045-1046, Grand Entry for Listeria
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AC4	Mattila-Sandholm, DEMONSTRATION PROJECT FAIR2 CT96-1028, Oct. 3,
	1997, pgs. 11-15, Novel methods of probiotic research
AD4	Collins, DEMONSTRATION FAIR CT96-1028, Nov. 15, 1996, pg. 27,
	Selection and safety criteria of probiotics
AE4	Arihara et al, LTRS IN APPL MICROBIOLOGY 22, 1996, pgs. 420-424,
	Salivacin 140, a novel bacteriocin from Lactobacillus
AF4	Collins et al, INT CONG & SYMP SERIES 219, pgs. 13-17, 1996,
	Probiotic bacteria - interaction with the human immune system
AG4	Daly et al, ANTONIE VAN LEEUWENHOEK 70, 1996, pgs. 99-110, Bio-
	technology of lactic acid bacteria with special reference to
AH4	Neutra et al, ESSENTIALS OF MUCOSAL IMMUNOLOGY, 196, pgs. 29-35,
	M Cells as a Pathway for Antingen Uptake and Processing
AI4	Collins, BOOK OF ABSTRACTS FROM EUR COMM BIOTECH & FAIR PROG,
	Oct 1995, pg. L2, Selection of Probiotic Strains and
AJ4	Collins, BOOK OF ABSTRACTS FROM EUR COMM BIOTECH & FAIR PROG,
	Oct 1995, pg. pA-3, Determination of stringent criteria
AK4	Lee et al, TRENDS IN FOOD & TECH, Vol 6, Jul 1995, pgs. 241-245,
	The coming of age of probiotics
AL4	Medaglini et al, PROC NATL ACAD SCI, Vol 92, Jul 1995, pgs. 6868
	-6872, Mucosal and systemic immune responses to a recombinant
AM4	Sarem-Damerdji et al, FEMS MICROBIOLOGY LTS 131, 1995, pgs. 133-
	137, In vitro colonization ability of human colon mucosa by
AN4	Shanahan, EXCERPTA MEDICA 13, 1995, pgs. 13-28, Pathogenic
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A04	Thornton et al, GASTROENTEROLOGY 108(4) A928-A928 Suppl. S, Apr.
	1995, Bile tolerance and bile salt hydrolase activity of
AP4	Brink et al, JOUR OF APPL BACTERIOLOGY 77, 1994, pgs. 140-148,
	Antimicrobial activity of lactobacilll: preliminary
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	AQ4	Thornton et al, IRISH JOUR OF MED SCI, June 3/4, 1994, 2 pgs.,
		Bile acid tolerance and deconjugating activity of lactobility
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		Towards an understanding of the survival mechanisms employed
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^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)